Remarks

The Applicants and the undersigned, Mr. Towsend, are very appreciative of the telephonic interview between Examiner Fernandez and the undersigned, Mr. Towsend, on February 10, 2006.

This AMENDMENT AFTER FINAL REJECTION is filed as a result of that telephonic interview.

All references and all grounds for rejection were discussed in the interview.

In this Amendment, the following claims are amended: Claims 25, 47, and 52.

In this Amendment, Claim 25 is amended to avoid the cited patents, most particularly those of Gross et al (5,356,632) and Hofmann (6,009,347).

In this Amendment, Claim 47 is amended to avoid the rejection based on 35 USC § 112.

In this Amendment, Claim 52 is amended to be in harmony with currently amended Claim 25.

In this Amendment, Claim 48 is cancelled since it recited a "needle" electrode which is now incorporated into currently amended Claim 25.

Entry of the foregoing amendment and reconsideration of the application in view of the above amendment and the following remarks is hereby requested.

Here is an overview of the status of all the claims in the present case.

Claims 25, 26, 28-31, 37, 38, 40, 42, 44, 47, 49, 50, and 52 are currently in this case.

Claims 1-24, 27, 32-36, 39, 41, 43, 45, 46, 48, and 51 are cancelled.

Claims 25, 47, and 52 are currently amended herein.

Claims 26, 49, and 50 remain in the case as originally filed.

The claims in the case which are independent claims are claims 25 and 52.

Original claims that have not been amended are ultimately dependent upon currently amended independent Claim 25.

With respect to the amendment of Claim 25, the following are important points.

a. The "needle" electrode is thoroughly disclosed in the patent application and is recited in now-cancelled Claim 48. Also, the "needle" having "a coating having at least one static layer of releasable molecules" provides a pre-coated electrode penetration structure which is not present in the Prior Art cited by the Examiner.

b. There is a clear recitation that the biological cells which receive the delivery of the releasable molecules from the electrode are in the tissues penetrated by the electrode.

c. There is a clear recitation that the electric field is applied to the tissues penetrated by the pre-coated electrode

which has "a coating having at least one static layer of releasable molecules".

With respect to the rejections of Claim 25, and claims dependent therefrom, it seems to the undersigned that the most significant grounds for rejection are based on the combination of Gross et al (5,356,632) and Hofmann (6,009,347). It seems to the undersigned that in making this rejection the Examiner is in essence alleging that Gross et al (5,356,632) discloses a pre-coated electrode that can be penetrated into a tissue, and that Hofmann (6,009,347) discloses an electrode that is penetrated into tissue that can be pre-coated.

It the purpose of these Remarks, in conjunction with the amendment to Claim 25, to argue for the removal of this ground for rejection. Simply stated, it is urged that, for a person with ordinary skill in the art, the device in Gross et al (5,356,632) is not penetrable into a tissue to be treated, and that Hofmann (6,009,347), for a person with ordinary skill in the art, teaches away from having any tissue-penetrating electrode that is pre-coated.

Specific facts and arguments are presented below.

Gross et al (5,356,632) is directed to a device having an electrode pair used for transdermal delivery of a drug through a patient's skin. The device is referred to as a "patch". It is well known that a "patch", used for transdermal delivery of a drug, does not penetrate the skin. Moreover, Gross et al

(5,356,632) specifically teaches that neither of the electrodes in the electrode pair should contact the tissue of the patient. Although, as stated by the Examiner, it is "possible" for the device of Gross et al (5,356,632) to "penetrate" the skin, such a penetration is clearly to be avoided by the Gross et al (5,356,632) device. Gross et al (5,356,632) teaches away from having the electrode contact the skin of the patient both before the drug is delivered to the patient and after the drug is delivered to the skin for transdermal delivery.

In this aspect of Gross et al (5,356,632), the Applicant's claimed invention is clearly different from the Gross et al (5,356,632) device. It is true, as the Examiner asserts, that with both the Gross et al (5,356,632) device and the Applicant's claimed invention, an electrode does not initially contact the patient's tissues. However, with the Applicant's claimed invention, once the releasable molecules are released from the electrode, the released molecules do not prevent contact of the tissues with the portion of the electrode under the released molecules. This aspect of the Applicant's claimed invention does not occur with the device of Gross et al (5,356,632) wherein even after molecules pass through the porous paper 14, neither of the pair of electrodes is permitted contact with the treated tissues.

More specifically, as stated in Gross et al, a layer of gel 13, containing the liquid drug to be delivered, may be applied over the two electrodes 11, 12, so as to be in direct contact with both electrodes and also to fill the gap 13 between both

electrodes. The opposite face of the gel layer 13, i.e., opposite to that facing the base sheet 10, is covered by a hydrophylic liquid-permeable sheet 14, preferably a sheet of porous absorbent paper. The device is to be applied with sheet 14 in direct contact with the skin 15 of the patient to receive the drug transdermally. [emphasis added].

An insulating layer (which is the hydrophylic liquid-permeable sheet 14) releasably contains a liquid drug to be delivered covering said gap and both of said electrodes, such that neither of said electrodes comes into contact with the subject's skin when applied thereto [emphasis added].

As stated in Gross et al, it is to be particularly noted that in the devices described, both electrodes contact the gel containing the drug to be delivered and neither electrode contacts the patient's skin [emphasis added]. This is to be distinguished from the iontophoresis technique for transdermal drug delivery wherein only one of the electrodes contacts the drug-containing medium and both electrodes contact the subject's skin. Accordingly, the transdermal drug delivery device constructed in accordance with the present invention provides the "control" advantage of the active patch, but not the disadvantage of the danger of electric shock, skin irritation or burns. The novel transdermal drug delivery device may therefore be called a "controlled passive patch" device [emphasis added].

Now turning to Hofmann (6,009,347), the Hofmann patent is directed to the arrangement and spacing of needle electrodes and the voltages applied to those needle electrodes. The needle electrodes are placed in a grid, and the voltages can be applied in a rotating pattern. There are two types of needle electrodes, both of which are used to penetrate tissues. One type of needle electrode is hollow, like a hypodermic needle; and the other type of needle electrode is solid throughout. The hollow needles are used to inject a treatment agent into the tissue to be treated.

By having hollow needles used for injection of drugs into tissues, there is clearly no need for any Hofmann electrode to be pre-coated with a "coating having at least one static layer of releasable molecules to be delivered into biological cells" such as provided by the Applicant's claimed invention. With the Hofmann (6,009,347) electrodes, having a pre-coated electrode would be unnecessary and superfluous.

In addition, there is no disclosure in Hofmann (6,009,347) of eliminating the hollow needles used for drug injection. Also, there is no disclosure in Hofmann (6,009,347) of using any kind of substitute for the hollow needles used for drug injection. With the use of hollow needles for drug injection, there is simply no motivation to have pre-coated electrodes.

As stated in Hofmann (6,009,347), referring specifically to FIG. 2, the illustrated connector template is shown in use in treatment of a prostate cancer or the like. In this instance, the

connector 22 is shown mounted on an elongated support rod 54 of an ultra-sound probe 56 which is shown inserted into the rectum of a patient. The sound probe is used to visualize the prostate and the location of the electrodes in the prostate. The template is then in a position such that a plurality of needle electrodes 58, 60 and 62 in a first row are inserted through three of the horizontal through bores, as illustrated, and into the prostate of the patient. In this instance, two of the needle electrodes, 58 and 62, are illustrated as being solid needle electrodes and a center electrode 60 is shown to be hollow to enable the injection of molecules, such as a drug or therapeutic agent or other material [emphasis added].

A second, or lower row of needle electrodes 64, 66 and 68 is directly below the aforementioned electrodes and extend through the through bores of the connector template and into the prostate of the patient. In this instance, two outer needles, 64 and 68, are hollow to enable the injection of a therapeutic or other agent into the prostate of the patient. [emphasis added]. These may be left in place following the injection of the therapeutic agent and serve as the electrodes for the application of the electrical pulses to the tissue of the prostate or cancer cells within the prostate.

The hollow needles 60, 64 and 68 have outlet ports at the tip, as illustrated. For example, needle 64 is shown to have outlet ports 70 and 72. Similarly, outlet ports in needles 60 and 68 are shown but not given reference numerals. [emphasis added]

Clearly, Hofmann (6,009,347) does not contemplate any type of a pre-coated electrode for administration of any drug for electroporation thereof.

As a matter of fact, Hofmann (6,009,347) discusses the prior art of electroporation with electrodes, and nowhere in the discussion of the prior art is there a disclosure of the Applicant's claimed invention of electrodes being coated with a coating having at least one static layer of releasable molecules to be delivered into biological cells.

More specifically, in the part of the specification of Hofmann (6,009,347) which discusses the prior art, Hofmann (6,009,347) states that with in vivo applications of electroporation, electrodes are provided in various configurations such as, for example, a caliper that grips the epidermis overlying a region of cells to be treated. Alternatively, needle-shaped electrodes may be inserted into the patient, to access more deeply located cells. In either case, after the implant agent is injected into the treatment region, the electrodes apply an electrical field to the region. [emphasis added].

Hofmann (6,009,347) also states that a number of experiments have been conducted to test therapeutic application of electroporation for cancer treatment in a process now termed electrochemotherapy. This treatment is carried out by infusing an anticancer drug directly into the tumor and applying an

electric field to the tumor between a pair of electrodes. [emphasis added].

IN SUMMARY, Gross et al (5,356,632), to a person with ordinary skill in the art, teaches away from a pre-coated electrode that is penetrated into a tissue into which the coating material is released from a tissue-penetrated electrode. Also, Gross et al (5,356,632) does not teach treating the biological cells in an electrode-penetrated tissue by the electrode-released material in an electric field at a tissue-penetrated electrode.

In addition, Hofmann (6,009,347) does not teach the use of a needle electrode, that is penetrated into tissue, that is pre-coated with any tissue treating agent. Moreover, in the four corners of Hofmann (6,009,347), there is no teaching of any way to administer a drug to be electroporated into biological cells in vivo other than the use of a hydrodermic needle, or the like, to inject or infuse a treating material into a tissue to be treated. Such limited treatment means disclosed in Hofmann (6,009,347), to a person with ordinary skill in the art, clearly teach away from employing a pre-coated needle electrode to penetrate tissues for administering a drug thereto.

No additional fees are required.

In view of the foregoing, it is respectfully requested that claims 25-26, 28-31, 37, 38, 40, 42, 44, 47, 49, 50, and 52 be

deemed allowable. If the Examiner believes otherwise, or has any comments or questions, or has any suggestions for putting the case in condition for final allowance, the Examiner is respectfully urged to contact the undersigned attorney of record at the telephone number below, so that an expeditious resolution may be effected and the case passed to issue promptly.

Respectfully submitted,

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Date

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